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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/726,463

12/03/2003

Richard Hayes

AQMED.0101

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EXAMINER

MOULTON, ELIZABETH ROSE

ART UNIT

PAPER NUMBER

3767

MAIL DATE

DELIVERY MODE

09/09/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/726,463	<b>Applicant(s)</b> HAYES ET AL.	
	<b>Examiner</b> ELIZABETH R. MOULTON	<b>Art Unit</b> 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 July 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1, 3-19, 22-24, 42-59 is/are pending in the application.
- 4a) Of the above claim(s) 1, 3-19, 22-24 and 59 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 42-58 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/9/09</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9 July 2009 has been entered.
2. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

***Election/Restrictions***

1. Applicant's election without traverse of group II, method claims 42-58 in the reply filed on 5 January 2009 is acknowledged. Claims 1, 3-19, 22-24 and 59 are withdrawn from consideration

***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 42-50 and 52-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abbot (US 5,588,816) in view of McWhorter et al (US 4,044,757) Abbott teaches a method of providing targeted drug delivery comprising the steps of:

Providing a fluid pumping system (Fig 1)

Inserting a catheter (18) into a circulatory vessel (aortic root or coronary sinus) proximal to said target organ (the heart)

Receiving a supply of a first fluid (blood 14) into said fluid pumping system

Pumping the first fluid at a measured rate to first delivery line (78)

Metering a pumping a given amount of a second fluid (crystalloid, Fig 2) to a second delivery line (80), wherein the second fluid contains medication (crystalloids) and is delivered at a rate that is tied to the first delivery rate (see Abstract "A control panel is operatively connected for adjusting the ratio of blood and second fluid delivered")

Delivering said first and second fluids through said catheter directly to the target organ at the same time (via catheter 18), producing a local therapeutic effect while minimizing systemic effects (because the heart is isolated from the body's circulatory system)

Abbott does not teach that the first and second fluids are not co-mingled until delivery into said catheter; instead they mix very slightly in outlet port 82 which connects to catheter 18, Fig 2.

McWhorter teaches a catheter for delivery two medications from separate pumps (Fig 8) where the first (120) and second (122) fluids lines are kept separate until delivery in to the patient (either through a dual lumen catheter 118/116 or a single lumen catheter (114) the joins the first and second lines as in Fig 4-7).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the catheter arrangement of McWhorter with the cardioplegia system of Abbott to inject multiple fluids without mixing and without introduction of air into the system (McWhorter abstract).

As to claim 43, see Abbott 31; claims 44, 56 Abbott 48, 50; claim 45 Abbott 42,44; claims 46, 49, 57 Abbott 46; claims 47, 58 Abbott 84 and 86; claim 48, Abbott 74, 76;

claim 50, Abbott 52; claim 52, McWhorter Fig 4-7; claims 53,54 McWhorter Fig 8; claim 55, Abbott 32 and 33;

2. Claim 51 is rejected under 35 U.S.C. 103(a) as being unpatentable over Abbott/McWhorter in view of Gillies et al. (PN 6,272,370).

Abbott/ McWhorter discloses the invention as recited in claim 42 however, fails to disclose said pumping step pumps adenosine.

Gillies et al. teaches that it is conventional in the art for said pumping step to pump adenosine (See Column 23 Lines 51-60).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have pumped adenosine as taught by Gillies et al. in the Abbott/McWhorter device since it would improve catheter-based administration of medicine.

### ***Response to Arguments***

1. Applicant's arguments with respect to claims 42-58 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELIZABETH R. MOULTON whose telephone number is (571)272-9970. The examiner can normally be reached on part-time R and F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ELIZABETH R MOULTON/  
Examiner, Art Unit 3767

/Kevin C. Sirmons/

Supervisory Patent Examiner, Art Unit 3767